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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,307	10/16/2001	Ganapati R. Mauze	10003714	7843

7590 04/10/2006

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/982,307	Applicant(s) MAUZE ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on March 13, 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Interpretation

1. Prior to examination, the claims must be analyzed, since claim construction precedes application of the statutory requirements for patentability.

The limitation that the fluid reservoir is connected to two tubes and also serves as a “waste reservoir” requires interpretation. The requirement that two tubes are connected is structural and is addressed in the rejection below. The functional requirement that the fluid reservoir serve as a “waste reservoir” represents an intended use for this claimed product. As MPEP 2111.02 notes “Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” It is clear that a structural difference must exist between the claimed invention and the prior art to overcome the rejection and not simply a difference in the intended use. As MPEP 2111.02 also notes “a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.”

Claim Rejections - 35 USC § 112 – second paragraph

2. Claims 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by the phrase "less than about 50 microliters". The phrase "less than" typically indicates a maximum point. The phrase "less than" however, is contraverted by the term "about" which implies that values above and below 50 microliters are permitted. Further, the extent of variance permitted by "about" is unclear in this context, since no ranges for "about" are given. In Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (CAFC 1991), the CAFC stated, "The district court held claims 4 and 6 of the patent invalid because their specific activity limitation of "at least about 160,000" was indefinite". After review, the CAFC states "We therefore affirm the district court's determination on this issue." Thus, the CAFC found the phrase "at least about" indefinite where the metes and bounds of the term were not defined in the specification. The term "less than about" suffers from the same flaw since the metes and bounds are unclear.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes “ If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen* , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).”

Here, the amendment to claim 21 of the phrase “having a liquid volume capacity of at least twice the liquid volume capacity of said associated sensing cartridge” is apparently new matter. A careful review by the examiner of the specification failed to identify any support for this new limitation. In fact, a word search of the word “reservoir”, “capacity” and of “volume” failed to identify any support for a “fluid reservoir” with twice the liquid volume capacity of an associated sensing cartridge, where the reservoir is connected to the sensing cartridge. The closest support found by the examiner, (since none was pointed out by Applicant) at page 5, which refers to relative sizes of the sensing and companion cartridges, lacks any support for the word “twice” and also lacks any support for the required connection relationship between the two cartridges. Therefore, the amendment appears to represent new matter.

The phrase “less than about 50 microliters” also appears to represent new matter. While there is express basis for the range of “20-50” at page 5, the phrase “less than” will include volumes below 20 microliters for which there is no support. As MPEP 2163.05 notes in referring to *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) “A corresponding new claim limitation to “at least 35%” did not meet the description

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requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement." The same logic applies in the current situation where the phrase "less than" causes the claim to read literally on embodiments outside the disclosed 20-50 microliter range and therefore this amendment does not comply with the written description requirement and is new matter.

Since no basis has been found to support the new claim limitation in the specification, the claim is rejected as incorporating new matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 21-23, 26-34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (U.S. Patent 5,922,591).

Anderson teaches a "cartridge" (see figure 3 and column 2, lines 20-44) and an analytical instrument (see figure 3) of claim 21 which comprises

A base element that can be "mated with" an analysis device (see column 15, lines 15-18), where Anderson expressly teaches that the reaction chamber portion can be "mated with a reusable base unit (see column 33, line 32 and see lines 30-59)" which provides some elements. As shown in figure 5, the device of Anderson has a top and bottom side.

Anderson teaches examples of elements that have 5 microliters, which is less than about 50 microliters (see column 40, line 28) as well as providing significant discussion regarding miniaturized analytical elements (see column 18, lines 10-44).

Anderson further teaches the presence of an entry port (see column 20, lines 61-65, where an inlet port for the entire device is taught) which is necessarily aligned with the base unit that encompasses fluid transport (see column 33, lines 29-30, for example).

A fluid reservoir (see column 33, lines 31-59 and see column 20, lines 64-65, where a "storage chamber" is discussed),

And where these are in fluid communication using a fluid transport system (column 2, line 35),

Where the cartridge performs an operation including a hybridization reaction chamber (see column 2, lines 28-35), or an amplification chamber used for PCR amplification (see column 10, lines 25-49).

As noted previously, Anderson teaches that the "cartridge" may be connected to a sensing "cartridge" either directly or indirectly (see column 15, lines 15-18) and is thereby shaped to interact with the remainder of a "diagnostic instrument".

Anderson further teaches the limitation that the fluid reservoir is connected to a first tube and that the fluid reservoir can also be a waste reservoir and is connected to a second tube. Anderson teaches, in figure 4, a fluid reservoir numbered 402 which is connected to three lines as shown in panel A. In Panel B, Lipshutz shows the same device, but where the "waste reservoir" and the "storage reservoir" are both connected

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to each other and to two tubes. This description meets the structural requirements of the claim.

Anderson also teaches an example where one chamber is more than twice the volume capacity of another chamber (see column 41, lines 10-14, where one chamber had a volume of 2.5 ul while another chamber had a volume of 10 ul).

Finally, Anderson expressly teaches that larger volume storage vessels may be present on the base and fluidly connected to the device (see column 38, lines 20-29).

With regard to claim 22, Anderson teaches the use of a fluid interface such as capillary electrophoresis for detection (see column 15) as well as by a mechanical/electrical interface into a reader device (column 17, lines 23-35).

With regard to claims 23, Anderson teaches a reagent storage system in the cartridge which are connected to fluid channels (see column 20, lines 60-65).

With regard to claims 26-28, 36, Anderson teaches thermocycling to perform PCR in fluid communication with a reservoir (see column 8, line 55 to column 9, line 42 and column 20, lines 60-65).

With regard to claims 29, 32, 33, Anderson teaches fluid transport systems (see column 2, line 35, for example) (Claims 32 and 33 do not structurally delimit the device since no structural element is included which effects the process step of mixing).

With regard to claim 30, Anderson teaches fluid systems which transport fluid to some chambers thereby increasing their volume (see column 2, lines 20-44).

With regard to claim 31, Anderson teaches a waste retrieval system (see figures 4A-C, where element 414 is the waste reservoir).

With regard to claim 34, Anderson teaches a device in which a sensor device and a companion cartridge are integrated on a single device in fluid communication with one another (see figure 3, for example).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 24, 25, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (U.S. Patent 5,922,591) in view of Leiner et al (U.S. Patent 6,037,178).

Anderson teaches the limitations of claims 21-23, 26-34, and 36 as discussed above. Anderson does not teach the use of calibration cartridges.

Leiner teaches the use of calibration cartridges (see abstract and column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a calibration cartridge as taught by Leiner with the device of Anderson since Liener states "It is an object of the present invention to propose methods of quality control and quality control liquids which will permit first a control measurement and then measurement of a specimen by means of one and the same single-use cartridge, in addition to providing information on the reliability of the analyzer, or rather, reliability and accuracy of the individual sensors contained in the single-use cartridge (see column 3, lines 45-51)." So an ordinary practitioner would have been motivated to include a calibration cartridge in order to improve the reliability and accuracy of the device. Further, it would have been prima facie obvious to use reservoirs in common for common reagents in order to minimize the number of separate solutions necessary to store in the device.

Response to Arguments

10. Applicant's arguments filed March 13, 2006 have been fully considered but they are not persuasive.

Applicant argues that Lipshutz does not teach a fluid reservoir is detachably removed from the sensor cartridge as well as the requirement that the volume is twice as large in the reservoir relative to the sensing cartridge. Since Anderson is a CIP of Lipshutz, these arguments are not entirely moot and will be addressed. Anderson teaches the differential size of chambers, teaching that chambers may differ more than two fold in size as shown at column 41 discussed above.

With regard to the issue of a teaching of storage compartments in the base linked to the sensing cartridge, Anderson expressly teaches the presence of 5 larger volume storage vessels in the base which are fluidly connected to the sensing cartridge (see column 38, lines 20-28).

Therefore, Anderson teaches the elements that were missing from the Lipshutz reference and anticipates the claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

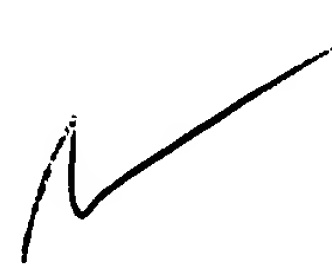
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey Fredman
Primary Examiner
Art Unit 1637

4/10/06